

Applicants: Arlindo L. Castelhana, et al.  
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**Remarks**

Claims 76-110, 114-124, 126-131 and 133-135 were pending in the subject application. By this amendment applicants have canceled claims 126 and 127 and have amended claims 76, 123, 124 and 133. Accordingly, claims 76-110, 114-124, 128-131 and 133-135 are currently pending.

**Double Patenting - Claims 76, 99, 124, 126-131, 133-135**

On pages 2-7 of the February 11, 2004 Office Action, the Examiner rejected claims 76, 99, 124, 126-131, 133-135 under the judicially created doctrine of obviousness-type double patenting. In particular, the Examiner alleged that 1) claim 76 is unpatentable over claims 1-7 of U.S. Patent No. 6,686,366; 2) claim 99 is unpatentable over claims 1 and 4-6 of U.S. Patent No. 6,686,366; 3) claims 124 and 126-131 are unpatentable over claims 22-29 of U.S. Patent No. 6,686,366; 4) claims 133-135 are unpatentable over claims 41-46 of U.S. Patent No. 6,686,366; 5) claim 76 is unpatentable over claims 7 and 8 of U.S. Patent No. 6,680,322; 6) claims 124, 127 and 129-131 are unpatentable over claims 29-33 of U.S. Patent No. 6,680,322; and 7) claim 133 is unpatentable over claim 36 of U.S. Patent No. 6,680,322.

In response, with respect to the obviousness-type rejection of claims of the subject application over the claims of U.S. Patent No. 6,686,366, applicants contend that the compounds claimed in the subject application are later filed improvements over the compounds claimed in the '366 patent. Applicants further note that claim 76 of the subject application is directed to the improved compounds which have substituents in the R1 position as recited in claim 76. Thus, claim 76 is a sub-genus of the genus defined by claim 1 of the '366 patent which sub-genus is specific to compounds having the later filed improvements. Similarly, the overlap between claim 76 and claim 6 of the '366 patent is

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directed to compounds having the later filed improvements.

For the Examiner's convenience, applicants point out that U.S. Patent No. 6,686,366 is a continuation-in-part of PCT International Application No. PCT/US99/12135. The subject matter claimed in the '366 patent is entitled to the priority date of the PCT International application. The improved compounds of the subject application also appear in the disclosure of the application which matured into U.S. Patent No. 6,686,366 but are not claimed in the '366 patent. The improved compounds are not entitled to the PCT International application date, but rather have an effective filing date of December 2, 1999, the same filing date as the subject application. The improved compounds are claimed in subject application which has as effective U.S. filing date of December 2, 1999.

With respect to the obviousness-type rejection of claims of the subject application over claims of U.S. Patent No. 6,680,322, Applicants have amended claims 76 and 133 to exclude the compounds of claims 7 and 8 of the '322 patent. Consequently, applicants contend that there is no longer any overlap with the claims of the '322 patent.

In view of the preceding discussion, applicant respectfully request that the Examiner reconsider and withdraw this double patenting rejection in its entirety.

**Claim Objections - Claims 124, 126 & 127**

On page 7 of the February 11, 2004 Office Action, the Examiner objected to claim 124 because the claim reads "a pharmaceutical composition comprising a the compound ...".

In response, applicants have deleted the extra "a" from the

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claim. Accordingly, the Examiner's objection is now moot.

In addition, the Examiner objected to claims 126 and 127 under 37 C.F.R. 1.75(c) as being of improper dependent form.

In response, without conceding the correctness of the Examiner's argument or relinquishing their right to pursue patent protection for any canceled subject matter but merely to advance prosecution of the subject application, applicants have canceled claims 126 and 127. Accordingly, the Examiner's objection is now moot.

**Rejection Under 35 U.S.C. §112, Second Paragraph - Claim 123**

On pages 7-8 of the February 11, 2004 Office Action, the Examiner rejected claim 123 under 35 U.S.C. §112, second paragraph, alleging that the claim fails to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In particular, the Examiner alleged that while the claim is drawn to a combination therapy, it does not recite any therapeutic steps which are to be practiced in the therapy.

In response, without conceding the correctness of the Examiner's argument or relinquishing their right to pursue patent protection for any canceled subject matter but merely to advance prosecution of the subject application, applicants have amended claim 123 to recite a pharmaceutical composition. Accordingly, the Examiner's rejection should now be moot.

**Rejection Under 35 U.S.C. §102(a) - Claim 76**

On pages 8-9 of the February 11, 2004 Office Action, the Examiner rejected claim 76 under 35 U.S.C. §102(a), alleging that the claim is anticipated by the disclosure of Campbell et al. In particular, the Examiner alleged that when R5 and R6 are methyl and R1 is acetamido ethyl, the compound of claim 76 corresponds

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to the compound disclosed in Campbell et al.

In response, without conceding the correctness of the Examiner's argument or relinquishing their right to pursue patent protection for any canceled subject matter, applicants have amended claim 76 to require that when R1 is acetamido then R5 is (1-methyl-pyrrolidin-2-ylmethyl)-phenyl-amine. Consequently, the compound disclosed by Campbell et al. is not within the scope of amended claim 76. Accordingly, applicants respectfully request that the Examiner reconsider and withdraw this rejection.

#### **Form PTO-1449**

Applicants received an initialed Form PTO-1449 along with the February 11, 2004 Office Action. However, one reference on page 7 of the Form PTO-1449 was not initialed. The Examiner indicated that the citation for the reference did not have a date.

Applicants attach hereto as **Exhibit A** a substitute Form PTO-1449 containing a complete reference for the Kiichiro et al. reference. In addition, applicants note that they have not yet received an initialed Form PTO-1449 for their Fourth Supplemental Information Disclosure Statement, filed on June 2, 2003. For the Examiner's convenience, Applicants attach hereto as **Exhibit B** a copy of the Form PTO-1449 submitted with applicant's June 2, 2003 Information Disclosure Statement. Applicants respectfully request that the Examiner initial both Form PTO-1449's and return copies for applicant's files.

#### **Conclusion**

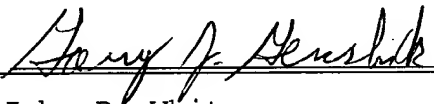
Applicants respectfully submit that the accompanying amendments and remarks serve to place all of the pending claims in condition for allowance.

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If a telephone interview would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorney invites the Examiner to telephone him at the number provided below.

No fee is deemed necessary in connection with the filing of this Amendment. However, if any fee is required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 03-3125.

Respectfully submitted,



I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to:  
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